POSTERS

TCT-229

First Report of A Novel Polymer-Free Dual-Drug Eluting Stent in De Novo Coronary Artery Disease: Results of the First in Man BICARE Trial

Mengyue Yu, Bo Xu, Yongjian Wu, Hongbing Yan, Jue Chen, Jie Qian, Chaowei Mu, Fenghuan Hu, Weixian Yang, Shubin Qiao, Yuejin Yang, Run-Lin Gao
National Center for Cardiovascular Diseases of China and Fu Wai Hospital, Beijing, China

Background: Durable polymers used for first-generation drug-eluting stents potentially contribute to persistent inflammation and late stent thrombosis. BICARE (Lepu Medical, Beijing, China) is a novel polymer-free stent system with nano technology and elutes rapamycin (1.6μg/mm2) and probucol (0.8μg /mm2). The first in man study aimed to evaluate the preliminary feasibility and safety of the BICARE stent.
Methods: Patients with stable or unstable angina, or prior myocardial infarction (MI), with single de novo native coronary stenosis < 30mm in length in vessel sizes ranging from 2.5 to 4.0 mm were enrolled at a single institution. The primary endpoint was target lesion failure (TLF) at 30-day defined as the composite of cardiac death, target-vessel MI (Q and non-Q), or ischemia-driven target lesion revascularization. Secondary endpoints include in-stent late lumen loss by quantitative coronary angiography and proportion of uncovered or malapposed stent struts by Optical Coherence Tomography (OCT) at 4-month, and TLF at 4, 12, 24 and 36-month follow-up.
Results: A total of 32 patients (age 55.7±8.7 years, male 62.5%, diabetes 18.8%) were enrolled consecutively in 1 month. The average baseline reference vessel diameter is 2.85±0.48 mm and the lesion length is 15.0±5.6 mm. There was no TLF at 30-day. All of the patients (100%) underwent angiographic follow-up at 4-month. The in-stent late loss was 0.14±0.19 mm, and the in-segment binary restenosis rate was 3.1%, respectively. The complete strut coverage was 98.2% by OCT with only 0.2% strut malapposition at 4-month among 16751 analyzed struts. There was no TLF at 4-month.
Conclusion: The preliminary feasibility and safety of the BICARE dual-drug polymer-free stent are demonstrated in the first in human study. OCT findings indicated excellent stent strut coverage at 4-month. Further pivotal randomized trial will confirm if this early results could translate into longer term safety and efficacy benefits.

TCT-230

BIOSOLVE-I Optical Coherence Tomography (OCT) Results of Cohort 1 with the First Drug Eluting Absorbable Metal Scaffold (DREAMS)

Jacques Koolen[1], Inge Wijnbergen[1], Raimund Erbel[2], Dirk Böse[2], Michael Haude[3], Hubertus Degen[3], Paul Erne[4], Francesco Prati[5], Paul Vermeersch[6], Stefan Verheye[6]
[1]Catharina Ziekenhuis, Eindhoven, Netherlands; [2]Westdeutsches Herzzentrum, Essen, Germany; [3]Städtische Kliniken-Neuss, Lukaskrankenhaus, Neuss, Germany; [4]Luzerner Kantonsspital, Luzern, Switzerland; [5]Rome Heart Research, Rome, Italy; [6]ZNA Middelheim, Antwerp, Belgium

Background: Absorbable magnesium scaffolds (AMS) are attractive as they only leave behind the healed, natural vessel, allowing restoration of vasoreactivity with the potential for vessel remodelling once bio-absorbed. Using optical coherence tomography (OCT), bioabsorption of a Drug Eluting Absorbable Magnesium Scaffold (DREAMS) can be characterized in humans.
Methods: BIOSOLVE-I is a prospective, multicenter first in man trial with follow-up investigations at 1, 6, 12, 24 and 36 months. Twenty-two patients were enrolled in cohort 1 with an imaging follow-up at 6 months and 24 patients were enrolled in cohort 2 with an imaging follow-up at 12 months. A subgroup of the patients were investigated by OCT. From the 22 patients enrolled in cohort 1, paired post-procedure and 6-month follow-up OCT images are available for 4 patients. Additional 10 patients had a 6-month follow-up OCT investigation only.
Results: The twenty-two subjects of cohort 1 included 16 males and 6 females with a mean age of 65.8 ± 10.4 years ranging from 42 to 77 years. Hypertension (86.4%), hyperlipidemia (81.8%), were the major cardiovascular risk factors and history of myocardial infarction was present in 40.9% of the subjects. Type A (50.0%), Type B1 (45.5%) and Type B2 (4.5%) lesions were treated with a 3.25 / 16 mm (50.0%) or a 3.5 / 16 mm (50.0%) Evaluation of OCT images are ongoing and will be available upon presentation.
Conclusion: Acute OCT investigation showed stent placement and visual appearance that is similar to a permanent metallic stent. The 6-month follow-up OCT images revealed continued degradation of the scaffold.

TCT-231

One-Year RESULTS OF THE MULTICENTRIC, DOUBLE-BLINDED, RANDOMIZED, VESTASYNC II TRIAL

Jose De Ribamar Costa[1], Alexandre Abizaid[1], Ricardo Costa[1], Breno Almeida[2], Marcos Perim[2], Fausto Feres[1], Fábio Sandoli de Brito[2], Luiz fernando Tanajura[1], Andrea Abizaid[1], Amanda Sousa[1], J Eduardo Sousa[1]
[1]Interventional Cardiology, Instituto Dante Pazzanese / HCOR, São Paulo, Brazil; [2]Hosp Sta Marcelina, São Paulo, Brazil

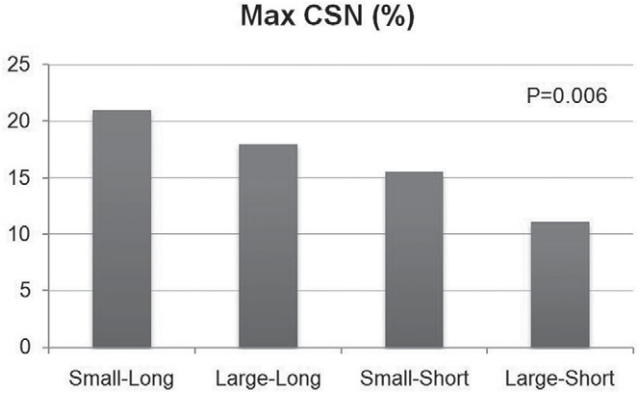
Background: Durable polymers in 1st generation DES have been linked to local coronary inflammation that could ultimately result in life-threatening adverse events. Polymer-free DES systems have been developed as an attractive alternative to minimize these undesired effects. We sought to assess the safety and efficacy of the novel VESTAsync™ Eluting Stent (VES) combining a Cro-Co platform with a nanothin-microporous hydroxyapatite surface coating impregnated with a polymer-free low-dose of Sirolimus (55μg).
Methods: The Vestasync II trial is a randomized (2:1), double-blinded multicenter comparison of the VES to its platform, the Gen X stent, with microporous hydroxyapatite surface coating but without sirolimus. Patients were eligible if they presented single de novo lesions in native coronary arteries with 3.0-3.5mm diameter and ≤ 14mm in length. Primary endpoint was 9-month in-stent late loss and % of stent obstruction. Lifelong AAS and 6-month clopidogrel were prescribed to all pts.
Results: A total of 75 patients were enrolled (50 treated with the DES). Baseline characteristics included mean age of 57 years and 23% of diabetics, with no differences between groups. RVD and lesion length were 2.67 ± 0.4mm and 14.0 ± 2.0mm. Procedure success was obtained in all cases. Three patients (4.2%) presented non-Q wave MI during hospitalization with no other MACE. After discharge, there were two cases of TLR(one in each group) and no MI, death or stent thrombosis. At nine months, the DES had a late loss of 0.39mm vs. 0.74mm with the non-eluted version (p=0.03). By IVUS, % of stent obstruction was 9% with the DES vs. 17% with the BMS (p<0.001).
Conclusion: The preliminary results of the Vestasync II trial demonstrate efficacy and midterm safety of these novel polymer-free DES. Further long term assessment in more complex cohorts is warranted.

TCT-232

Impact of Stent Size and Length on Neointimal Hyperplasia After Resolute Zotarolimus-Eluting Stent Implantation: Insights From RESOLUTE Trials

Ryotaro Yamada[1], Teruyoshi Kume[1], Katsuhisa Waseda[1], Hideki Kitahara[1], Kenji Sakamoto[1], Paul G Yock[1], Ian T Meredith[2], Martin B Leon[3], Laura Mauri[4], Aran C Yeung[1], Yasuhiro Honda[1], Peter J Fitzgerald[1]
[1]Division of Cardiovascular Medicine, Stanford University Medical Center, Stanford, CA; [2]Monash Heart and Medical Centre, Clayton, Australia; [3]Columbia Univ Medical Center/ New York Presbyterian Hospital, New York, NY; [4]Harvard Medical School, Boston, MA

Background: Previous studies have revealed that stent diameter and length correlate with restenosis or cardiovascular events after stenting. The purpose of this study was to assess potential impact of stent size and length on neointimal hyperplasia (NIH) after Resolute zotarolimus-eluting stent (ZES) implantation.
Methods: From the Stanford University IVUS Core Laboratory database, 151 de novo coronary lesions treated with Resolute ZES were enrolled in this analysis. The lesions were divided into 4 groups, based on stent volume index (cutoff: 6.0 mm^3/mm, range: 3.2 to 13.0 mm^3/mm) and total stent length (cutoff: 24 mm, range: 12 to 54 mm): Small-Long (n=13), Large-Long (n=50), Small-Short (n=29), and Large-Short (n=59) stent groups. Neointimal obstruction was calculated as neointima/stent volume. Cross-sectional narrowing (CSN) was defined as neointima/stent area.
Results: Baseline patient characteristics were similar among the 4 groups. At 8-9 months, the 4 groups showed no significant difference in overall neointimal obstruction (6.7±6.2, 4.6±3.9, 4.7±5.4, 3.6±5.2%, respectively, p=0.22) or mean NIH thickness. Incidences of significant lumen encroachment (max CSN >50%) and late-acquired incomplete stent apposition were also not statistically different. On the other hand, significant differences were detected in max CSN among the groups. Overall, regression analysis showed a positive correlation of max CSN with total stent length (p=0.004), whereas a correlation with stent volume index did not reach statistical significance (p=0.182).



Conclusion: Pooled IVUS analysis of RESOLUTE trials suggests total stent length as the primary determinant of maximum lumen encroachment by neointima, rather than stent size. In this population, however, this effect did not significantly impact the overall amount of neointima or other clinically relevant IVUS variables.